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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,919	03/12/2004	John P. Donoghue	08790.0012	7030
22852	7590	03/28/2006		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,919

Applicant(s)

DONOGHUE ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54, 58-61, 63-115 and 118-151 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 20-22, 26-39, 48-50, 54, 58-61, 63-77, 82-84, 88-99, 105-111, 115 and 119-126 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02222006</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 16-19,23-25,40-47,51-53,78-81,85-87,100-104,112-114 and 127-151.

DETAILED ACTION

Information Disclosure Statement

1. The IDS submitted on 2/22/2006 is accepted. Accordingly, the listed reference has been considered.

Claim Objections

2. The amendments to claims 58, 60, 66, 99, and 119 in response to various informalities are acknowledged and accepted. The objections to claims 58 and 99 are withdrawn.

Claim Rejections - 35 USC § 112

3. The amendments to claim 60 is acknowledged and accepted. Furthermore, Applicant's traversal of the 112(2) rejection of claim 106 is moving. The rejections of claims 60 and 106 under 35 U.S.C. 112(2) are withdrawn.

Response to Amendment

4. The cancellation of claims 55-57, 62, and 116-118 is acknowledged.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59-61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Pless et al. (US 2003/0004428 hereinafter "Pless"). Please note that Fischell et al. (US 6,016,449 hereinafter "Fischell") has been incorporated by reference into the Pless disclosure. Although reference is given to the Fischell reference below, this is only done for Applicant's convenience in referencing the document. Because of the incorporation by reference, **all** listed claims are rejected under the Pless reference only.

7. In regards to claims 1 and 64, Pless discloses an implantable device comprising a means to detect signals indicative of activity preceding an event (422) and a processing unit to predict a neurological event (428 and abstract). Furthermore, the event detection algorithm incorporated by Pless and disclosed by Fischell comprises storing a target signal indicative of activity preceding a neurological event, in the form of a threshold. Examiner is interpreting a threshold as a constant level signal that is inherently set by some previous signal. Additionally, this threshold is compared to detected signals (Fig. 5A-5D) and is indicative of an activity that precedes a neurological event (a "fully-developed" epileptic seizure, see col. 5, line 4).

8. In regards to claims 2 and 65, Pless discloses that the implant is configured to be placed in the patient's brain (224).

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9. In regards to claims 3-5 and 66-68, Pless discloses that the implant includes a multi-electrode array (412, 414, 416, and 418) that penetrates into the neural tissue (par. 0080), and are recording and stimulating electrodes (422 and 424).

10. In regards to claims 6 and 69, Pless discloses that at least one electrode detects electrical signals indicative of activity preceding the event (par. 0088).

11. In regards to claims 7 and 70, Pless discloses that the electrode is proximate the implant (224, Fig. 2).

12. In regards to claims 8, 9, 71 and 72, Fischell discloses that the processing unit converts the signals into a recognizable pattern (Fig. 5A-5D) and the pattern includes a formula describing the behavior in time (col. 16, line 43) and space (the 3 electrode traces correspond to 3 points in space).

13. In regards to claims 10 and 73, Fischell discloses that individual neuron signals are isolated from neighboring signals (Fig. 5A-5D). Please note that the Examiner is interpreting "individual neuron signals" as being individual signals corresponding to one or more neurons.

14. In regards to claims 11 and 74, Pless discloses that the signals include spikes (Fig. 9, element 910).

15. In regards to claim 12, Pless discloses that the processor characterizes a pattern of neuronal activity to predict the event (pars. 0088 and 0108).

16. In regards to claims 13 and 75, Pless discloses that the implant is placed proximate the neural focus. Please note that Examiner is interpreting proximate as being close enough to measure the electrical activity.

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17. In regards to claims 14 and 76, Pless discloses that the implant inherently capable of measuring local field potentials, or any other electrical potentials.

18. In regards to claims 15 and 77, Pless discloses that the implant detects EcoG signals (par. 0013).

19. In regards to claims 20, 21, 82 and 83, Fischell discloses that the implant comprises a subdural grid with a multi-electrode array (col. 2, line 59).

20. In regards to claims 26-28, 58, 88-90, 119, and 120, Fischell discloses that signals preceding a neurological event are characterized, stored, and compared to detected signals. Additionally, the target signal is modified over time adaptively (col. 16, line 54 through col. 17).

21. In regards to claims 29-32 and 91-93, Pless discloses that the device comprises a recording device (426), detects biological signals (abstract), comprises a sensor to detect other signals and communicates with the processor (par. 0112), and compares the signals detected by the implant with the other signals (par. 0112).

22. In regards to claims 33 and 94, Pless discloses that the processor differentiates activity preceding the event from normal activities (par. 0035).

23. In regards to claims 34-38, Fischell discloses that the processor outputs information related to the patient's condition (col. 7, line 43), including an indicator, which is an external device (11) that has a visual indicator (80).

24. In regards to claims 39 and 95-99, Fischell discloses an output device that is external, displays information, and includes a warning signal (col. 7, line 58).

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25. In regards to claims 48-50 and 108-111, Fischell discloses that the processor generates a control signal to suppress the event with electrical current to the central nervous system (col. 2, line 52).

26. In regards to claims 54 and 115, Fischell discloses that the impedance is reduced between electrodes (col. 4, line 43).

27. In regards to claims 59, 61 and 122, Fischell discloses that the event is an epileptic symptom, which is inherently undesired (abstract).

28. In regards to claim 60, the implant is located at an epileptic focus (col. 27, line 62).

29. In regards to claim 63, Pless discloses that "readiness potential" is measured because his device measures how ready the brain is to have a seizure.

30. In regards to claims 105 and 106, Fischell discloses causing movement of a portion of the patient's body comprising a stimulating signal (col. 7, line 63). Please note that the movement is vibration and is inherently felt by the patient.

31. In regards to claim 121, Fischell discloses determining whether an event occurred, whether it was mistakenly predicted, and modifying the target signal based on whether the event was mistakenly predicted (col. 19).

32. In regards to claim 123, Fischell discloses that the implant is proximate the epileptic focus (col. 3, line 4).

33. In regards to claims 124-126, Fischell discloses that the signals are preprocessed, comprising calibrating detected signals based on background signals (col. 15, line 1), and includes filtering (col. 14, line 63).

Claim Rejections - 35 USC § 103

34. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

36. Alternatively, claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59, 61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless in view of Abraham-Fuchs et al. (US 4,974,602, hereinafter "Abraham-Fuchs"). Pless discloses the essential features of the claimed invention except for explicitly specifying that the target signals be previously detected. Abraham-Fuchs teaches of providing a system for recognizing neurological events by comparing a detected signal to a previously detected template signal indicative of activity preceding a neurological event (abstract) to allow recognition of pathologies with high patient-to-

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patient variability (col. 1, line 41). Therefore, it would have been obvious to provide Pless' invention by comparing a detected signal to a previously detected template signal indicative of activity preceding a neurological event to allow recognition of pathologies with high patient-to-patient variability.

37. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pless or Pless in view of Abraham-Fuchs. Pless (or Pless in view of Abraham-Fuchs) discloses the essential features of the claimed invention except for explicitly indicating that movement is caused to a finger of a patient. Pless does disclose applying stimulation to the median nerve (col. 7, line 62). Further, it is well known in the art to apply a suprathreshold stimulation to nerves to cause movement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Pless (or Pless in view of Abraham-Fuchs) by providing a suprathreshold stimulation to the median nerve to induce movement of a finger to indicate impending seizure.

38. Claims 22 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pless (or Pless in view of Abraham-Fuchs) in view of Gliner (US 2003/0074032 hereinafter "Gliner"). Pless (or Pless in view of Abraham-Fuchs) discloses the essential features of the claimed invention except for providing a movement sensor to detect movement of the brain. Gliner teaches of providing a movement sensor (par. 0036) to more accurately detect seizure activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Pless' (or

Pless in view of Abraham-Fuchs) invention with a movement sensor to more accurately detect seizure activity.

Response to Arguments

39. Applicant's arguments filed 2/22/2006 have been fully considered but they are not persuasive. As described above, Examiner is interpreting Pless' threshold as a "previously detected signal indicative of the activity that precedes the neurological event". Alternatively, Applicant's arguments are moot based on the new grounds of rejection, necessitated by amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK



3/23/06

^ c
GEORGE R. EVANISKO
PRIMARY EXAMINER

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